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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,073	12/07/2001	Anthony M. Jevnikar	024916-011	8806
75	90 09/26/2003	· .		
Teresa Stanek Rea BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			EXAMINER	
			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	_
			DATE MAILED: 09/26/2003	>

Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No. Ap

ication No. Applicant(s) 10/005,073

Jevnikar et al.

Examiner

Office Action Summary

G.R. Ewoldt, Ph.D.

rt Unit **1644** 



• •	on the cover sheet with the correspondence address				
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM					
THE MAILING DATE OF THIS COMMUNICATION.					
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailting date of this communication.					
- If the period for reply specified above is less than thirty (30) days, a reply within the					
<ul> <li>If NO period for reply is specified above, the maximum statutory period will apply a         <ul> <li>Failure to reply within the set or extended period for reply will, by statute, cause the</li> </ul> </li> </ul>	he application to become ABANDONED (35 U.S.C. § 133).				
<ul> <li>Any reply received by the Office later than three months after the mailing date of the earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	this communication, even if timely filed, may reduce any				
Status					
1) Responsive to communication(s) filed on <u>Dec 7, 20</u>	001				
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This act	tion is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.					
Disposition of Claims					
4) 💢 Claim(s) <u>52-101</u>	is/are pending in the application.				
	is/are withdrawn from consideration.				
5)  Claim(s)	is/are allowed.				
6) Claim(s)	is/are rejected.				
7)	is/are objected to.				
8) 💢 Claims <u>52-101</u>	are subject to restriction and/or election requirement.				
Application Papers					
9) $\square$ The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are	e a) $\square$ accepted or b) $\square$ objected to by the Examiner.				
Applicant may not request that any objection to the d	Irawing(s) be held in abeyance. See 37 CFR 1.85(a).				
11) The proposed drawing correction filed on	is: a) $\square$ approved b) $\square$ disapproved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Exami	iner.				
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) □ All b) □ Some* c) □ None of:					
1. Certified copies of the priority documents hav	re been received.				
2. $\square$ Certified copies of the priority documents hav	e been received in Application No				
3. Copies of the certified copies of the priority de application from the International Bure.	ocuments have been received in this National Stage au (PCT Rule 17.2(a)).				
*See the attached detailed Office action for a list of the					
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
a) The translation of the foreign language provisional application has been received.					
15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).				
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449) Paper No(s).	5) Notice of Informal Patent Application (PTO-152)				
3) [ miormation Disclosure Statement(s) (PTO-1449) Paper No(s)	6)				

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## DETAILED ACTION

- 1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 52-62, 72-77, 84-87, and 97-101, drawn to a method for suppressing or reducing the immune response, or suppressing the rejection of engrafted tissue or, preventing the development of an autoimmune disease, classified in Class 424, subclasses 184.1 and 185.1.
- II. Claims 63-71, 78-83, and 95-96, drawn to a plant tissue and a pharmaceutical composition thereof, classified in Class 424, subclasses 184.1 and 185.1.
- III. Claims 88-94, drawn to transgenic plant or edible tissue thereof, classified in Class 435, subclass 468 and Class 800+.

The inventions are distinct, each from the other because:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in materially different processes, such as for *in vitro* assays.

- 3. Inventions II and III are different products. They are distinct because they comprise different components with different structures and modes of action.
- 4. Because these inventions are distinct for the reasons given above and Groups I-III have acquired a separate status in the art as shown by their different classification and/or the searches are not co-extensive, and because the Groups encompass divergent subject matter, restriction for examination purposes as indicated is proper.
- 5. Additionally, this application contains inventions drawn to patentably distinct species. Applicant is required under 35 U.S.C. § 121 to elect:
- A) a single autoantigen or protein such as one of those listed in Claims 57 or 74,

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- B) and list all Claims readable thereon including those subsequently added. Currently all claims are generic.
- 6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The different autoantigens or proteins comprise different amino acid sequences with different structures. Said antigens would elicit different immune responses. Accordingly, the compositions and methods of the instant application are independent and patentable over one another.

- 7. Applicant is advised that the response to this requirement to be complete must include an election of the species to be examined even though the requirement be traversed.
- 8. Any inquiry concerning this communication from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

G.R. Ewoldt, Ph.D.

Primary Examiner

Technology Center 1600

September 24, 2003